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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,171	05/04/2006	Ulrike W. Klueh	MTT/101/PC/US	4607

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EXAMINER
SCHULTZ, JAMES

ART UNIT	PAPER NUMBER
1633	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,171	KLUEH ET AL.	
	Examiner	Art Unit	
	James D. (Doug) Schultz	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,9,14-16,19,25,28,37-39,51,59,66 and 68-86* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,9,14-16,19,25,28,37-39,51,59,66 and 68-86* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 15, 2010 has been entered.

Status of Application/Amendment/Claims

Claims 1, 2, 9, 14-16, 19, 25, 28, 37-39, 51, 59, 66, and 68-86, filed March 15, 2010, are pending, and are the subject of the present Official action.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 11/25/2009 and 3/15/2010 were filed before the mailing date of the instant action on the merits. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner, and signed and initialed copies are enclosed herewith. It is noted that the IDS of 3/15/2010 provided a reference cited with no publication source, date or volume information. This reference has been struck through as not being considered since it has not been cited properly. See M.P.E.P. 609.

Notice of Non-compliant Amendment

The reply filed on March 15, 2010 is not in compliance with 37 CFR § 1.121.

§ 1.121(c) Manner of making amendments in applications.

(c) Claims . Amendments to a claim must be made by rewriting the entire claim with all changes (e.g., additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).

Note that "Previously Canceled" is not a proper claim designation. In order to avoid prosecution delay associated with the mailing of a Notice of Non-compliance, applicant is advised to review this rule carefully towards compliance in future submissions. The claim set of March 15, 2010 is examined herein, since it is clear that "Previously Canceled" is equivalent to "Canceled".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 86 recites the limitation "the biological tissue" in claim 70. There is insufficient antecedent basis for this limitation in the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 9, 14-16, 19, 25, 28, 37-39, 51, 59, 66, and 68-86 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The examiner is unable to locate support for the biological matrix in contact with both an outer surface of the implantable device and with a biological system. Should applicants disagree, applicants are invited to respond with specific page and line numbers where such support might exist in the specification as filed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 9, 14-16, 19, 25, 28, 37, 39, 51, 66, 68-70, 72, 73, 75-82, and 84 are rejected under 35 U.S.C. 102(e) as being anticipated by Sayler et al. (U.S. Patent No.: 6,673,596; filed Dec 2, 1999). This rejection is repeated for the reasons of record first set forth in the Official action mailed February 19, 2009, but also includes new claims 79-82, and 84. The rejection is restated below, and is followed by a response to applicants Request for Reconsideration.

The claims encompass an artificial tissue system, comprising a matrix configured for biological contact with an implantable device and a plurality of cells supported by said matrix.

Sayler et al. teach an in vivo biosensor device comprising a genetically engineered bioreporter for detecting glucose, glucagon or insulin target analytes in the body of an animal; the bioreporter device encapsulated on an integrated circuit. Sayler teaches controlled drug delivery systems capable of being directly or indirectly controlled by the detection device that provide drugs such as insulin to the animal in response to the amount of target analyte present in the body fluids (Title and Abstract; limitation of claims 14, 15 and 68).

Sayler et al. further teach that the monitoring and regulating the level of analytes may be carried out in the tissues and circulatory system of a human (first column, lines 22-24; limitation of claims 9 and 39). The bioreporter preferably comprises a plurality of eukaryotic cells that produce a reporter polypeptide in response to the presence of the target analyte. Exemplary mammalian cells are human cells such as islet β -cell, or immortal stem cells, comprising one or more nucleic acid segments that encode the reporter polypeptide (column 3, lines 54-66; limitation of claims 2, 4, 70, 72 and 73).

Sayler et al. additionally teach that the biosensor may consist of bioengineered living cells entrapped or encapsulated in a polymeric matrix, or in suspension behind a semi-permeable membrane. Examples of matrices include sol-gel or microporous hydrogels (column 23, lines 34-53). Biochips may be coated with Matrigel, a basement membrane material that promotes attachment of epithelial cells. An alternate approach suspends the cells in Matrigel and allows it to form a gel on the surface of the biochip. The cells are then immobilized in the basement membrane material (column 35, lines 42-47; limitation of claims 1, 16, 20, 25, 27, 28, 37, 51, 52,

54, 69, 75, 79-82 and 84).

Sayler et al. state that post-transplantation host-rejection effects can be minimized through immunoisolation techniques by enclosing non-host cells in hydrogel membranes; and that host rejection of the implanted biosensor is not a an issue if cells from the host are used for the biosensor construction (column 25, lines 14-17 and 26-27; limitation of claims 3, 19 and 67).

Therefore by teaching all the limitations of the claims, Sayler et al. anticipate the instant invention as claimed.

Response to Request for Reconsideration

Applicants traverse the instant rejection and have provided a declaration under 37 CFR 1.132 from inventor Donald Kreutzer. Both the arguments and the declaration assert that Sayler's use of Matrigel is used inside the bioreporter device, not as a surface coating in contact with body tissue. Both applicants arguments and the declaration assert that Matrigel is employed as a glue in the disclosure of Sayler to support cells in a compartment that applicants assert must be covered by a semi permeable membrane or its equivalent. Since the compartment is inside a semi permeable membrane, applicants assert that the device of Sayler does not meet the limitation whereby the biological matrix (i.e. Matrigel) is in contact with an outer surface of the implantable device and with a biological system. Applicants point to a portion of the Sayler disclosure that relates to Matrigel: "Biochips may be coated with Matrigel, a basement membrane material that promotes attachment of epithelial cells. An alternative approach suspends the cells in Matrigel and allows it to form a gel on the surface of the biochip. The cells are then immobilized in the basement membrane material and are not subject to dislodgement by friction." From this, applicants assert that the Matrigel clearly is not in contact with the

biological tissue in which their device is implanted. Applicants provide four reasons for their assertion that one would need to use a semi permeable membrane as a container for their device. Again, applicants argue that the need for a semi permeable membrane prevents the device of Sayler from meeting the claim limitation that the Matrigel be in contact with both an outer surface of the implant double device, and with a biological system.

These arguments have been fully considered, but are not convincing. Applicants argue limitations that are not present in the claims. For example, applicants assert that the biological matrix (i.e. Matrigel) is used inside the bioreporter device, and not as a surface coating in contact with body tissue. However, there is no requirement in the claims that the biological matrix is in contact with both an outer surface and **body tissue**. Instead, the claims merely recite that the biological matrix must be in contact with the outer surface of the device and a "biological system".

Furthermore, the interpretation of what exactly constitutes the "outer surface of the implantable device" may be very broad. For example, the "implantable device" could be interpreted as the sensor and its container (or semi-permeable membrane of Saylor). This would be the interpretation that applicants appear to favor. Alternatively, the "implantable device" could be interpreted as simply as the sensor itself. The latter interpretation is also entirely reasonable, considering Sayler refers to the sensor alone as the implantable device (col. 3, lines 39-42). Applicants do as well, in their arguments. For example, on page 12 of the response dated March 15, 2010, applicants define a "biocompatible container" as the "container that contains the entire implantable device…". Again at page 16, "the implantable device 'preferably is contained in a biocompatible container….". Thus, since both applicants arguments and the Sayler reference

describe the sensor alone as the implantable device, regardless of whether there is a container or semi-permeable membrane encasing it, and since Sayler clearly teaches Matrigel attached to the sensor's outer surface, Sayler is reasonably considered to teach a biological matrix (Matrigel) in contact with an outer surface of an implantable device.

In further contrast to applicant's arguments, the biological matrix is also considered to be in contact with a biological system. Applicants acknowledge throughout their arguments that Sayler's device is in contact with body fluid (i.e. blood plasma), as evidenced by the arguments that the device of Sayler would not withstand immune system targeting, among other arguments. However, it is applicants position that the presence of a semi permeable membrane prevents Sayler's device from contacting body tissue. Notwithstanding the fact that nowhere in the claims is there a requirement for contacting body tissue, it is further set forth that blood plasma is a part of the circulatory system, which is considered to be a biological system. It is maintained that the device of Sayler, covered with Matrigel and assuming arguendo the presence of a semi-permeable membrane, is nevertheless in contact with the biological system relating to blood plasma. Thus the Matrigel of Sayler is considered to be in contact with both the implantable device and a biological system, as required by the claims. There is nothing in any of the claims that prevents or excludes the presence of a semi permeable membrane. Thus, all arguments that rely on the notion that the Matrigel of Saylor is not in contact with both the outer surface of the implantable device and a biological system due to an alleged requirement for a semi-permeable membrane are not considered convincing.

Furthermore, applicants argue that Saylor teaches away from the use of Matrigel in the absence of a semi-permeable membrane are not convincing, since the notion of "teaching away"

is considered only under 35 U.S.C. § 103(a), whereas the present rejection was made under 35 U.S.C. § 102(e). In addition, the teaching away argument is based on the premise that the alleged requirement for a semi-permeable membrane is excluded by the present claims. As discussed above, the instant claims are not considered to exclude the presence of such a container/semi-permeable membrane.

Applicants also argue that Matrigel cannot be considered to be the semi-permeable membrane that is allegedly required by the Sayler disclosure, nor can the polymer matrix or hydrogel of Sayler be considered such. Applicants provide various reasons for these assertions. However, as explained above, whatever semi-permeable membrane Sayler is alleged to require would nevertheless provide for the passage of blood plasma inside the "container" (or semi-permeable membrane), where the Matrigel (which is adhered to the implantable device of Sayler) then contacts the blood plasma (i.e. a biological system), thus meeting the disputed claim limitation.

Applicants assert that the disclosure of Sayler does not teach the presence of cells that extend the functional lifespan of the sensor, as required in claims 1 and 28. It is noted that the functional limitations of "extending the functional lifespan of the sensor" would be met by the barest of lifespan extensions, such as a few minutes, hours, or days. It is also noted that the comparison by which any such extension would be measured has not been defined, and may be thus defined reasonably broadly as one of ordinary skill in the art would. Sayler teaches the coating of their sensor device with Matrigel that have cells of their invention embedded therein. Specifically, Sayler teaches the use of cells derived from the patient in which their device would be implanted. Such cells would be considered to extend the functional lifespan of the sensor as

compared with cells that are heterologous, thus meeting this limitation. For at least these reasons, the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 9, 14-16, 19, 25, 28, 37-39, 51, 59, 66, and 68-86 28, 37, 38, 59, 66, 70, 71, 74, 75, 83, 85, and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sayler et al. (U.S. Patent No.: 6,673,596; filed Dec 2, 1999), in view of Soykan et al. (U.S. Patent Application Publication 2001/0000802; effective filing date: Dec. 20, 2000). This rejection is repeated for the reasons of record first set forth in the Official action mailed February 19, 2009, but also includes all new claims, 79-86. The rejection is restated below, and is followed by a response to applicants Request for Reconsideration.

The invention of claims 1, 2, 9, 14-16, 19, 25, 28, 37, 39, 51, 66, 68-70, 72, 73, 76-82, and 84 is considered to be unpatentable in view of Sayler as discussed above. Sayler further forms the basis for the present rejection. Claims 28, 37, 38, 59, 66, 70, 71, 74, 75, 83, 85, and 86

embrace an artificial implant system, comprising an implantable device, a matrix configured for biological contact with said implantable device and a plurality of cells supported by said matrix, wherein the matrix is a cell culture derived basement membrane, wherein the cells induce cellular growth and neovascularization, and wherein the implant system further comprises a system for testing the effectiveness of said implant.

Sayler et al. describe an in vivo biosensor device comprising a genetically engineered bioreporter for detecting glucose, glucagons or insulin target analytes in the body of an animal; the bioreporter device encapsulated on an integrated circuit. Further teaching controlled drug delivery systems capable of being directly or indirectly controlled by the detection device that provide drugs such as insulin to the animal in response to the amount of target analyte present in the body fluids (Title an Abstract).

Sayler et al. state the bioreporter preferably comprises a plurality of eukaryotic cells that produce a reporter polypeptide in response to the presence of the target analyte. Exemplary mammalian cells are human cells such as islet β-cell, or immortal stem cells, comprising one or more nucleic acid segments that encode the reporter polypeptide (column 3, lines 54-66). Sayler et al. additionally state that the biosensor may consist of bioengineered living cells entrapped or encapsulated in a polymeric matrix, or in suspension behind a semi-permeable membrane.

While Sayler et al. do not specifically describe the cells as inducing cellular growth and neovascularization, and the implant system further comprising a subsystem, such was known in the prior art.

Soykan et al. describe an implantable system that includes a carrier and eukaryotic cells, which produce and release a therapeutic agent and a stimulating element for stimulating the

release of the therapeutic agent. The system can also include a sensing element for monitoring a physiological condition and triggering the stimulating element to stimulate the delivery device to release the therapeutic agent (Abstract). Soykan et al. state that the drug-eluting cells can be genetically engineered autologous endothelial cells that line the walls of blood vessels, that secrete vasodilatory, thrombolytic or angiogenic factors, such as vascular endothelial growth factor (VEGF), (paragraphs [0031] and [0034], p. 4; paragraph [0042], p. 5; limitation of claims 38, 71 and 74).

Soykan et al. further describe their implant as further comprising a second polymer composition coating at least a portion of the first polymer composition and cells containing a coagulation inhibitory or anti-inflammatory compound (paragraph [0062], pp. 7-8, bridging; limitation of claim 59).

With respect to the implant further comprising a subsystem configured to test the effectiveness of the artificial tissue system Soykan et al. state that the systems of the present invention include a second implantable device that includes a stimulation element, preferably in contact with a sensing element, and monitors the patient and detects when a stimulus needs to be sent to the cells to trigger release of one or more therapeutic agents (paragraph [0069]; p. 8). As the implant comprises a sensor, the second implantable device constitutes a subsystem sensor that monitors the effectiveness of the implant.

It should be noted that endothelial cells are a component of vascular structures and VEGF is well known for its inherent ability to promote neovascularization, and must necessarily do so in the biological system.

As stated in MPEP 2112, the express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102 or 103. "The inherent teaching of a prior art reference, a question of fact, arises both in the context of anticipation and obviousness." In re Napier, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed. Cir. 1995). Moreover, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference.

"When the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent." See MPEP 2112.01 or In re Best, 195 USPQ 430, 433 (CCPA 1997). As stated in MPEP 2112: The express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102 or 103. "The inherent teaching of a prior art reference, a question of fact, arises both in the context of anticipation and obviousness." In re Napier, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed. Cir.1995) (affirmed a 35 U.S.C. 103 rejection based in part on inherent disclosure in one of the references). See also In re Grasselli, 713 F.2d 731, 739, 218 USPQ 769, 775 (Fed. Cir. 1983).

The teachings of Sayler et al. and Soykan et al. are directed to implants and tissue systems comprising genetically altered cells. Therefore, it would have been prima facie obvious for a person of ordinary skill in the art, to combine their respective teachings and to genetically alter the implanted cells to secrete VEGF to induce cellular growth and neovascularization, as instantly claimed, with a reasonable expectation of success, at the time of the instant invention. A person of ordinary skill in the art would have been motivated to utilize endothelial cells

transformed with a VEGF gene in the implant system of Sayler et al., because such was expressly taught by Soykan et al. to deliver a therapeutic product to a patient.

Response to Request for Reconsideration

Applicants have traversed the instant rejection by pointing to the alleged deficiencies of the Sayler patent. However, the Sayler patent is not considered to be deficient as discussed above. The secondary reference of Soykan is alleged by applicants to not disclose cells that extend the functional lifespan of the sensor, as recited in claims 1 and 28 of the present application. However, this limitation is considered to be taught by Sayler as discussed above. Furthermore Soykan is alleged to not disclose a matrix material comprising cell culture derived basement membrane that is in contact with both a sensor and biological system. Again, this limitation is considered to be taught by Sayler and is discussed above.

Regarding allegations of the invention satisfying longfelt needs, it is first set forth that such arguments could not be considered convincing against the independent claims, which are considered anticipated as discussed previously. Secondary considerations may only be considered against rejections under 35 U.S.C. § 103(a). Regarding the specific assertions that the claimed technology enables glucose sensors to be used more economically, and to require fewer insertions into the skin of a patient each month, it is noted that no evidence has been presented to substantiate these conclusions.

Per M.P.E.P. 2141: "….Such evidence, sometimes referred to as "secondary considerations," may include evidence of commercial success, long-felt but unsolved needs, failure of others, and unexpected results. The evidence may be included in the specification as filed, accompany the application on filing, or be provided in a timely manner at some other point

during the prosecution. The weight to be given any objective evidence is made on a case-by-case basis. The mere fact that an applicant has presented evidence does not mean that the evidence is dispositive of the issue of obviousness." Per M.P.E.P. 2145: "A showing of unexpected results must be based on evidence, not argument or speculation. In re Mayne, 104 F.3d 1339, 1343-44, 41 USPQ2d 1451, 1455-56 (Fed. Cir. 1997)."

While the declaration under 37 CFR 1.132 filed March 15, 2010 establishes that there is a long-felt need for implantable devices that assist in glucose monitoring and insulin regulation, the declaration is insufficient to overcome the rejection of the present claims as set forth in the last Office action because there is no evidence that if persons skilled in the art who were presumably working on the problem knew of the teachings of the above cited references, they would still be unable to solve the problem. See MPEP § 716.04. Furthermore, it is not clear that the present invention actually solves the problem, or merely represents an improvement on the results produced by the efforts of others. Establishing long-felt need requires objective evidence that an art recognized problem existed in the art for a long period of time without solution. However, the declaration states in paragraph 3 that there are short duration transdermal glucosesensors on the market that are approved for up to 7 days. While it is acknowledged that the present declaration asserts that coating the presently claimed sensors extends their life from 5 days to 2 weeks, it appears that the coating is the same as that disclosed in the prior art, and would thus flow from such teachings. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. (Doug) Schultz whose telephone number is (571)272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James D. (Doug) Schultz, PhD/
Primary Examiner, Art Unit 1633